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APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTY DOCKET NO
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EXAMINER

ART UNIT	PAPER NUMBER
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14

DATE MAILED:

This is a communication from the examiner in charge of your application.  
COMMISSIONER OF PATENTS AND TRADEMARKS

### OFFICE ACTION SUMMARY

Responsive to communication(s) filed on 6/14/1999

This action is FINAL.

Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

#### Disposition of Claims

Claim(s) 36-39, 41-47, 62, 66-67, 69-70 is/are pending in the application.  
Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
 Claim(s) \_\_\_\_\_ is/are allowed.  
 Claim(s) 36-39, 41-47, 62, 66-67, 69-70 is/are rejected.  
 Claim(s) \_\_\_\_\_ is/are objected to.  
 Claim(s) \_\_\_\_\_ are subject to restriction or election requirement.

#### Application Papers

See the attached Notice of Draftsperson's Patent Drawing Review PTO-948.  
 The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.  
 The proposed drawing correction, filed on \_\_\_\_\_ is  approved  disapproved.  
 The specification is objected to by the Examiner.  
 The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. § 119

Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).  
 All  Some\*  None of the CERTIFIED copies of the priority documents have been  
 received.  
 received in Application No. (Series Code/Serial Number) \_\_\_\_\_  
 received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e)

#### Attachment(s)

Notice of Reference Cited, PTO-892  
 Information Disclosure Statement(s), PTO-1449, Paper No(s) \_\_\_\_\_  
 Interview Summary, PTO-413  
 Notice of Draftsperson's Patent Drawing Review, PTO-948  
 Notice of Informal Patent Application, PTO-152

--SEE OFFICE ACTION ON THE FOLLOWING PAGES--

1. Claims 36-39, 41-42, 45-47, 62, 66-67, 69-70 have been amended.  
Claims 40 and 68 have been canceled.  
Claims 48-61, 63-66, drawn to non-elected inventions, remain withdrawn.  
Claims 36-39, 41-47, 62, 66-67 and 69-70 are examined on the merits.
2. This application contains non-elected claims 48-61, 53-66. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.
3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
4. The objection to the specification, as not complying with 1.821(d) of the Sequence Rules and Regulations, is withdrawn in view of amendments to the specification.
5. The objection of claim 38, as not complying with 1.821(d) of the Sequence Rules and Regulations, is withdrawn. The objection of claim 70, as not complying with 1.821(d) of the Sequence Rules and Regulations, is maintained.
6. The objection of claim 38, because it improperly depends from canceled claims 1 and 2, is withdrawn.
7. The objection to claim 36, because it recites a trademark, is withdrawn.
8. The rejection of claims 36-47 and 68-70 under 35 U.S.C. § 101, because the claims are directed to non-statutory matter, is withdrawn.

9. The rejection of claims 36-39, 41-47, 62, 66-67, 69-70 under 35 U.S.C. 112, second paragraph, is maintained.

Amended claim 36 remains vague and indefinite in the recitation "repeat structures." The identity of the repeat structure that defines the claimed product remains unidentified. For example, the single nucleotide residues "A" is a structure and is repeated throughout any given polynucleotide sequence.

Claim 36 remains vague and indefinite in the recitation "corresponding mRNA species of different length comprising identical 3' regions but different 5' regions." For any given protein, encoded by one mRNA species, this statement is nonsensical.

Claim 37 remains vague and indefinite in the recitation "showing stable in vitro expression of the corresponding mRNA if allogenic spleen reaction is carried out with non-irradiated, not pretreated spleen cells of mouse strains CBA and C57Bl/6." It remains unclear how such patterns of expression limit the claimed protein.

Claim 38 remains vague and indefinite in the recitation "hybridizing." The applicant argues that the claims are drawn to "stringent" conditions, and thus the hybridization conditions are set forth. This is not found persuasive. The recitation "stringent" still encompasses a range of conditions and the metes and bounds of the claimed, hybridizing sequence remains unclear.

Rejections based on the following recitations are withdrawn in view claim amendments:

- "has to comply with at least the features a), b), c), and d)" (claim 36)
- "at least" and "may be" (claims 36)
- "may be isolated from" (claims 36, 39)
- "the cDNA encoding the protein" (claim 36)
- "corresponding mRNA" (claim 37)
- "fusion proteins each coding for a protein" (claim 42)
- "having at least differentiation-inducing activity on Friend erythroleukemia cell lines" (claims 42, 47, 62, 66 and 67)
- "comprised portions, analogues, and derivatives of said proteins" (claim 42)
- "an analogue, a derivative or portions thereof" (claim 62)

"having essentially purified, native form" (claim 43)  
"having essentially recombinant form" (claim 44)  
"having at least differentiation-inducing activity on Friend erythroleukemia cell lines and/or growth factor activity and/or colony-stimulating activity" (claim 45)  
"having at least differentiation-inducing activity on friend erythroleukemia cell lines" (claim 47)  
"therapeutic means" (claim 62)  
"effective amount" (claim 62)  
"the human or murine protein with at least .... activity" (claim 66)  
"synthetic protein" and "at least" (claim 67)  
"as a growth factor, colony-stimulating factor, a factor inducing erythropoiesis and/or inducing the immune system" (claim 69)  
"said protein comprises at least those amino acids which are encoded by nucleotide 74-154 or 155-685" (claim 70)

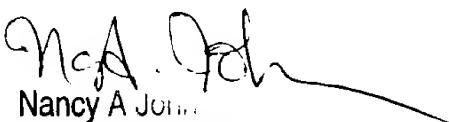
10. The rejection of claims 36-39, 41-47, 62, 66-67, 69-70 under 35 U.S.C. 112, first paragraph, is maintained. In view of the remaining claim rejections under 35 U.S.C. 112, second paragraph, discussed in the above paragraph, one of skill in the art can not make and use the claimed invention commensurate with the scope of the claims, with a reasonable expectation of success and without undue experimentation.

11. The rejection of claims 36, 37, 39, 42-47, 62, 66, 69 under 35 U.S.C. 102(b) as being anticipated by any of WO 89/04668, Eto (BBRC 142:1095, 1987) or Tsuji (Biotechnology and Bioengineering 31:675, 1988) is maintained. The rejection of claim 70 under 35 U.S.C. 102(b) as being anticipated by any of WO 89/04668, Eto (BBRC 142:1095, 1987) or Tsuji (Biotechnology and Bioengineering 31:675, 1988) is withdrawn. All three references disclose a protein that is the same as that claimed. The applicant argues that the cited references disclose proteins that are different at both the DNA and protein levels. This is not found persuasive. The applicant has not pointed to explicit differences between the disclosed protein and the broadly claimed protein. It is

noted that the optional limitations of claim 36 ("optionally . . .") are given no patentable weight for the application of the art. Further, when broadly interpreted, such claim limitations as the following: "having AT rich regions in the cDNA encoding the protein" (claim 17); "partial amino acid sequence" (claim 41); "variants of said protein comprising an amino acid sequence which is sufficiently similar" (claims 42 and 62); "comprises partial amino acid sequences according to SEQ ID NO:3 or SEQ ID NO:5 wherein one or more of the amino acids may be deleted, substituted, or added" (claim 47); and "comprises completely or in part the amino acid sequence" (claims 66-67) read on just about any protein.

12. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a). A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nancy Johnson whose telephone number is (703) 305-5860. The examiner can normally be reached on Monday through Friday from 8:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Paula Hutzell, can be reached on (703) 308-4310. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014 or (703) 308-4242. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

  
Nancy A. Johnson  
Primary Examiner

August 30, 1999